UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,502	01/03/2005	Christopher M Ward	021911.001110US	2720

20350 7590 03/21/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/520,502	**Applicant(s)** WARD ET AL.	
	Examiner Marcia S. Noble	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-6,8-10 and 14*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 3. NOTE: The amended claims now recite, "wherein 5T4 expression indicates differentiated cells". This raises new matter issues because the specification disclosed an invention that detects 5T4 antigen which is measuring changes in a stem cell that is undergoing the process of differentiation (ie-differentiating). However, the above process indicates that the stem cells are differentiated cells or have completed the process of differentiation. The specifcation does not provide supports for a stem cell expressing 5T4 antigen that has completed the process of differenitation as indicated by "differentiated cells". Furthermore, the most literal interpretation of the claims is stating that the stem cell is a differenitated cell. Neither the specification nor the art support a stem cell that is a differentiated cell. Therefore, an artisan would not know if the instant method lead to a stem cell or a differentiated cell. Therefore, because the amendement to the claims introduce this new matter issue, the amended claims are not being entered .

Continuation of 11. does NOT place the application in condition for allowance because:
SCOPE OF ENABLEMENT
Claims 1-6, 8-10, and 14 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising detecting the presences of 5T4 antigen in mouse embryonic stem (mES) cells or human embryonic carcinoma (hEC) cells comprising incubating a sample of mES cells or hEC cells with a labeled anti-5T4 antibody such that specific binding of the antibody to 5T4 cell surface antigen on mouse ES cells or hEC cells occurs and detecting and sorting of mES cells or hEC cells on the basis of presence or absence of 5T4 antibody following the incubation, does not reasonably provide enablement for a method of detecting the differentiation status of any stem cell comprising detecting the presence or absence of 5T4 antibody on the surface stem cells wherein the presence of 5T4 antigen represents stem cells in a more differentiated state and the absence of 5T4 antigen identifies undifferentiated or pluripotent stem cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant traversed this rejection on the grounds that examiner does not provide a prima facie against the claims. Applicant alleges that examiner does not understand the invention. Applicant states that the misunderstanding of the invention is that examiner believes that instant invention is directed to the absence of 5T4 antigen being a "marker" of pluripotenct stem cells and that this interpretation is in error because the claims feature the detection of 5T4 expression in stem cell and that the detection of 5T4 expression is used as an indication of differentiation status, where its expression indicates differentiated cells.

Applicants arguments have been fully considered but have not been found persuasive. It is acknowledged and understood that 5T4 antigen expression in stem cells is claimed as an indicator of differentiation status and it is acknowldged that that the intent of the claims is to detect 5T4 antigen in stem cells and this detection is claimed to indicate that the stem cells are differentiated. However, as previously stated in the enablement rejection of record, the specification does not support 5T4 antigen as an indicator of differentiation status or that its expression indicates differentiated cells as the amended claims. As previously stated in the rejects of record, the specification discloses a descriptive expression pattern of 5T4 agent expression in ES and EC cell in culture once LIF is removed. The specifcation also discloses that 5T4 antigen in expressed in chimeric mice embryos in all three germ layers. However, for a cell to be considered truly differentiated, it must be demonstrated that the stem cell has lost its pluritopency or multipotency. The specification does not teach that the ES cells in vitro or the cells present in the chimeric embryos that express 5T4 antigen have also lost pluripotency or multipotency. Therefore, an artisan would not know if the expression of 5T4 antigen truly indicates that the cells are differentiated as claimed. Therefore because Applicant's arguments do not overcome the scope of enablement rejection. The rejection is maintained.

112, SECOND PARAGRAPH
Claim 1-6 and 14 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitations of "low levels", negligible" and "reflect". The amendment to the claims would have removed these recitations and overcome the rejection. However, because the amended claims are not being entered. The rejeciton is maintained.

102 REJECTION

Claims 1, 3, 8, and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Southall et al (Br J Cancer 61:89-95, 1990).

Applicant traversed this rejection on the grounds that that amendment to the claims now require that the 5T4 postive stem cell be differenentiated which is opposite of the teaching of Southall et al which teaches that the 5T4 antigen cell are undifferentiated. These arguments would be found persuasive. However, because the amendments to the claims have not been entered, the claims still recite, "reflects differentiation status", which can be differntiated or undifferntiated, and therefore still encompass the 5T4 positive carcinoma cell disclosed by Southall et al. Therefore, the rejection of record is maintained.